

CLAIMS

1. A method of preventing or treating vasculoproliferative disease in vascular structures, which comprises the step of:

administering extravascularly and locally an antiproliferative effective amount of an antiproliferative agent to the vascular structure.

2. A method according to claim 1 wherein the agent comprises rapamycin.

3. A method according to claim 1 wherein the antiproliferative agent is administered perivascularly.

4. A method according to claim 1 wherein extravascular, local administration is accomplished by means of an implantable, antiproliferative agent eluting, perivascular vascular sleeve, the sleeve comprising a matrix material imbibed with the agent.

5. A method according to claim 4 wherein the sleeve is substantially circumvascular.

6. A method according to claim 4 wherein the matrix material comprises fibrin.

7. A method according to claim 4 wherein the agent comprises rapamycin and heparin.

8. A method according to claim 4 wherein the matrix material comprises collagen.

9. A method according to claim 4 wherein the matrix material comprises chitosan.

10. An implantable, antiproliferative agent-administering perivascular sleeve adapted to be placed in contact with the exterior of a vascular structure comprising:

a) A flexible, cylindrical, bioabsorbing, agent-eluting matrix material, the material having a vascular-sized lumen passing substantially through said matrix material, the matrix material having dispersed therein:

b) An antiproliferative agent.

11. The sleeve of claim 10 which further includes an support means, said means being circumferentially disposed about the exterior of the matrix material.

12. A method of treating vasculoproliferative disease in hemodialysis access sites which comprises the step of:

administering extravascularly and locally an antiproliferation effective amount of an antiproliferation agent to the access site.

13. A method of suppressing vasculoproliferative response in a vascular structure comprising the step of:

administering vascular extravascularly and locally an antiproliferation effective amount of an antivasculoproliferation agent to the vascular structure.

14. A method of treating smooth muscle cell (SMC) hyperplasia in vascular structures which comprises the step of:

administering, extravascularly and locally, an antiSMC effective amount of an anti SMC agent to the vascular structure.

15. A method according to claim 13 wherein the vascular structure is a hemodialysis access site.

16. A method according to claim 13 wherein the vascular structure is a vascular graft.

17. A method according to claim 13 wherein the vascular structure is a graft anastomatic site.

18. A method according to claim 13 wherein the vascular structure is a vein.

19. A method according to claim 13 wherein the vascular structure is a venous conduit or anastomatic site.

20. A method of preventing or delaying failure of a hemodialysis access site by the extravascular and local administration of agents that prevent suppress or treat vasculoproliferative response or SMC hyperplasia.

21. The method of claim 20 wherein the failure mode of the hemodialysis vascular access is selected from the group consisting of thrombosis, infection, foreign body reaction, luminal narrowing or occlusion of the anastamotic sites, narrowing or occlusion of the vein, artery or prosthetic conduits.

22. The method of claim 20 wherein the extravascular, local administration of agent is achieved by delivering drug from a drug eluting sleeve placed in contact with the access site.

23. The method of claim 22 wherein the sleeve is placed in contact with the access site by the securement techniques selected from the group consisting of suturing, stapling, gluing, or using a self-interlocking mechanism.

24. The method of claim 20 wherein the agent used to prevent, to suppress, or to treat hyperproliferative vascular disease is selected from the group consisting of rapamycin or rapamycin analogue, paclitaxel, paclitaxel analogue(s), other taxanes, tacrolimus, tacrolimus analogue(s), actinomycin D, dexamethasone, steroids, fractionated heparin, unfractionated heparin, metalloproteinase inhibitors, Flavoperidol, human autologous, heterologous vascular, bone marrow cells, other cells, stem cells, genetically modified human cells, IIBIIIA antagonists, and antibiotics.

25. The method of claim 22 wherein the sleeve is made from natural or synthetic polymers that are biodegradable.
26. The method of claim 22 wherein the sleeve is made of Type I Collagen.
27. The method of claim 22 wherein the sleeve comprises fibrin.
28. The method of claim 22 wherein the sleeve comprises chitosan.
29. The method of claim 22 wherein the sleeve comprises a biodegradable material.
30. The method of claim 22 wherein the sleeve comprises a non-biodegradable material.
31. The method according to claim 22 wherein the drug is combined with the sleeve matrix material using the method selected from the group consisting of, saturation, dispersion, and immobilization.
32. The method of claim 23 wherein the suture used to secure the drug eluting sleeve to the access site is coated with an antiproliferative drug.
33. An apparatus for local administration of agents for preventing or delaying failure of a hemodialysis vascular access site.

34. The apparatus of claim 33 comprising a collagen matrix material formed combined with a drug, the matrix material being formed into the shape of a spiral.
35. The apparatus of claim 34 with an interlocking feature.
36. An apparatus comprising a vascular graft combined with one or more antiproliferative drugs.